The Diagnostic Error Index: A Quality Improvement Initiative to Identify and Measure Diagnostic Errors

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Objective To develop a diagnostic error index (DEI) aimed at providing a practical method to identify and measure serious diagnostic errors.

Study design A quality improvement (QI) study at a quaternary pediatric medical center. Five well-defined domains identified cases of potential diagnostic errors. Identified cases underwent an adjudication process by a multidisciplinary QI team to determine if a diagnostic error occurred. Confirmed diagnostic errors were then aggregated on the DEI. The primary outcome measure was the number of monthly diagnostic errors.

Results From January 2017 through June 2019, 105 cases of diagnostic error were identified. Morbidity and mortality conferences, institutional root cause analyses, and an abdominal pain trigger tool were the most frequent domains for detecting diagnostic errors. Appendicitis, fractures, and nonaccidental trauma were the 3 most common diagnoses that were missed or had delayed identification.

Conclusions A QI initiative successfully created a pragmatic approach to identify and measure diagnostic errors by utilizing a DEI. The DEI established a framework to help guide future initiatives to reduce diagnostic errors. *(J Pediatr 2021;232:257-63)*.

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Diagnostic error in healthcare is a widespread and, until recently, an underappreciated problem.[1,2] It is estimated that diagnostic errors will contribute to 40 000-80 000 hospital deaths[3] and affect nearly 12 million individuals each year.[4] Missed or delayed diagnoses become the basis for some of the most common and costly medical malpractice claims. One study finds diagnostic errors to be the leading cause of death and disability claims and the highest proportion of total payments.[5] Also, diagnostic errors remain one of the leading causes of preventable harm.[6,7] Despite their recognized impact, measurement of diagnostic error remains a unique challenge facing many healthcare organizations.[8]

In 2015, the Committee on Diagnostic Error in Healthcare produced a report, *Improving Diagnosis in Health Care,* for the National Academies of Sciences, Engineering, and Medicine (NASEM), which concluded most people would experience at least 1 diagnostic error in their lifetime.[1] Their report defined a diagnostic error as the failure to establish an accurate and timely explanation of the patient's health problem(s) or communicate that explanation to the patient. Moreover, the Committee recognized that without a dedicated focus on improving the diagnostic process, diagnostic error would persist and worsen because of increasing healthcare complexity.

Although our hospital has strived to eliminate preventable harm, we lacked a systematic method for identifying diagnostic error.[9] Given the increased awareness of these potential safety events, executive leadership chartered a diagnostic error quality improvement (QI) team to reduce diagnostic errors as part of the institution's overall goal to achieve zero preventable harm. The team's charge was 4 fold: (1) develop a process for identifying and measuring diagnostic errors, (2) increase education regarding diagnostic errors, (3) determine best practices to improve critical

DEI	Diagnostic error index
QI	Quality improvement
NASEM	National Academies of Sciences Engineering and Medicine
NCH	Nationwide Children's Hospital
EHR	Electronic health record
RCA	Root cause analyses
M&M	Morbidity and mortality

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I.H. serves on the Editorial Board for *The Journal of Pediatrics*. The authors declare no conflicts of interest.

https://doi.org/10.1016/j.jpeds.2020.11.065

thinking and communication around diagnostic error, and (4) reduce diagnostic error and its associated patient harm.

For this QI study, we describe the process by which our QI team implemented a systematic methodology to identify and measure the number of diagnostic errors across a single pediatric academic center. This initiative included creating a diagnostic error index (DEI) to aggregate total diagnostic errors across the institution.

Methods

Nationwide Children's Hospital (NCH) is a free-standing, quaternary pediatric medical center in Columbus, Ohio, with over 500 inpatient beds. The hospital has over 90 000 emergency department visits, 18 000 inpatient discharges, and 1.5 million outpatient visits annually. The institution has 12 000 employees, with more than 1300 medical staff members. Each year, medical staff train more than 300 residents and fellows in 58 medical and surgical training programs. An integrated electronic health record (EHR) system (Epic Systems Corporation) is used in both inpatient and outpatient settings across the hospital system.

Interventions

Team Structure. The Associate Chief Medical Officer was tasked with creating a multidisciplinary diagnostic error QI team. This group consisted of 17 medical and surgical specialists from various disciplines, the Chief Medical Information Officer, a pediatric chief resident, and representatives from advanced practice nursing, pharmacy, and QI services.

Key Driver Diagram. The diagnostic error QI team identified 5 key drivers, derived from the team's charge and recommendations from the NASEM report[1]: (1) improve communication and collaboration among healthcare providers; (2) create a supportive environment in which to review and discuss diagnostic error; (3) provide feedback on diagnostic errors to clinicians; (4) create a culture of transparency regarding disclosure and discussion of diagnostic errors; and (5) enhance clinician education regarding the diagnostic process (Figure 1).

DEI Development. The team's initial focus was to develop a meaningful yet efficient method to identify potential diagnostic errors by prioritizing automated data collection from well-established domains to minimize time-intensive, manual chart review. The team chose domains that would potentially capture the most harmful diagnostic errors occurring to patients. Despite a widespread safety culture within our institution that encourages nonpunitive, voluntary reporting of near-misses, errors, and safety events, our team chose various domains to ensure case capture was not exclusively dependent on voluntary reporting, which may be incomplete and biased. The 5 locally available domains included (1) class I autopsy findings according to the Goldman classification system[10]; (2) institutional root cause analyses (RCA)[11]; (3) voluntary reporting through an electronic risk management system (CS Stars, LLC); (4) morbidity and mortality (M&M) conferences; and (5) an institutionally developed abdominal pain EHR trigger tool.[12]

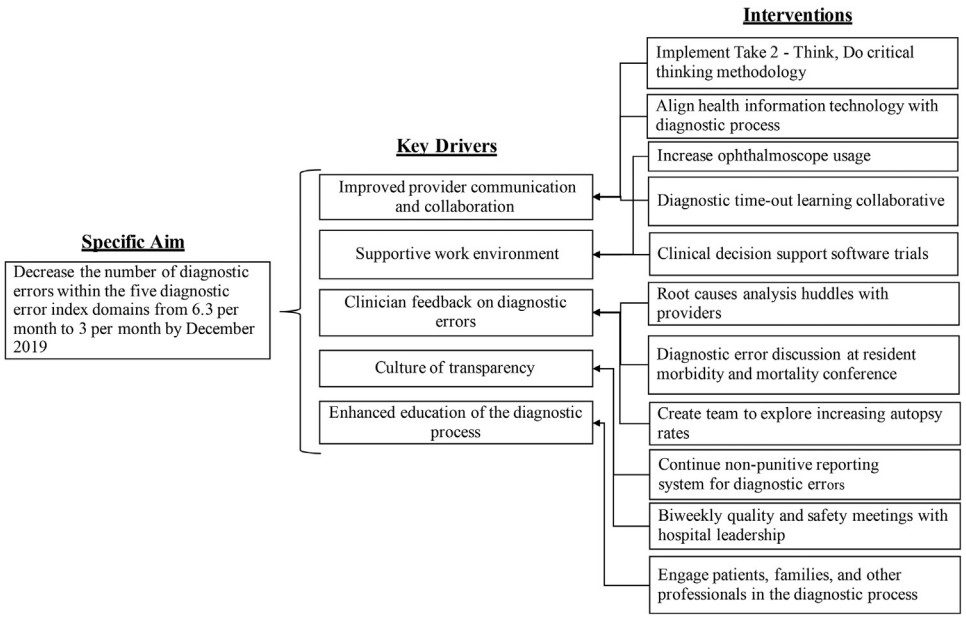

Figure 1. Key driver diagram.

Next, the team developed an outcome metric labeled the DEI, modeled after the preventable harm index.[9] The DEI represents a composite of confirmed diagnostic errors drawn from the aggregate of potential diagnostic errors identified in the 5 previously defined domains. Confirmation of potential diagnostic errors was determined through an adjudication process described below in further detail. All confirmed diagnostic errors were then summated in the DEI.

Domains of Potential Diagnostic Error. The diagnostic error QI team reviewed all class I autopsy findings, a potential source for diagnostic error highlighted by the *Improving Diagnosis in Health Case* report.[1] One study found that 10% of autopsies were associated with diagnostic errors that resulted in a class I autopsy finding.[13] Class I findings represent missed major diagnoses in which detection before death may have altered management or patient outcome.[10]

All institutional serious and precursor safety events are reviewed by executive leadership to determine the proper course of action. Events requiring an RCA follow the recommended methodology outlined by Healthcare Performance Improvement, a subsidiary of Press Ganey Holding, Inc.[11] This process includes the taxonomy of individual and system failure modes identified during event review. Following that taxonomy, individual failures categorized by the RCA review team as "situational awareness," "failure to validate/verify," "mindset," and "tunnel vision" were reviewed by the diagnostic error QI team.

Reporting systems are essential mechanisms for the identification and reduction of medical errors.[14] Events entered into our institution's electronic voluntary reporting system, CS Stars, are categorized into 30 different categories by dedicated QI staff. An automated report queries the "missed or wrong diagnosis" category each month and electronically sends identified reports to our team for review. NCH employees report over 8000 adverse or potentially adverse (near-miss) events each year, making it a valuable source of potential diagnostic errors.

A system-based M&M conference is "a patient safety strategy, both for surfacing adverse events and serving as a mechanism to understand causation."[15] Also, it is more effective than traditional event reporting at identifying diagnostic errors, communication problems, and workflow issues.[16] Our pediatric residency M&M program seeks to identify failures relative to standards of care and behavioral and safety tools that could have mitigated these errors. Often, patient cases selected for presentation demonstrate significant adverse events contributing to patients' unexpected or unintended M&M.

Abdominal pain is a frequent complaint among pediatric patients with a range of benign to life-threatening etiologies. Given the challenges abdominal pain presents, it invites opportunities for diagnostic error and breakdowns in the diagnostic process.[12] The purpose of the abdominal pain trigger tool was to capture missed serious abdominal pathology related to diagnostic error, which ultimately required either hospitalization or surgical intervention. A data analyst from QI services created an abdominal pain trigger report using our institutional enterprise data warehouse. This report generates a list of patients who presented each month to any NCH emergency department or urgent care center with a chief complaint of abdominal pain and were discharged home but returned within 10 days for unplanned hospitalization. The diagnostic error QI team reviewed each one of these patient cases identified by the trigger tool.

Diagnostic Error Adjudication Process. Each case identified from the 5 locally available domains underwent a review and adjudication process at monthly QI team meetings. The QI team leader and QI service line coordinator preliminarily reviewed cases before meetings to obtain necessary supplemental information and help serve as facilitators for group discussions. Attendees present for the adjudication process included members of the diagnostic error QI team to ensure multidisciplinary representation and input.

The adjudication process started with a summary of pertinent case details. The QI team utilized previously compiled event summaries for case review, including presentation slides for M&Ms and RCAs, pathology autopsy reports with class I autopsy findings, and voluntary event reporting follow-up and feedback reports. The abdominal pain trigger tool required manual chart review by the team leader and service line coordinator to obtain pertinent details required for adequate case adjudication. For all domains, if there was missing or inadequate case information, manual chart review was used to obtain additional details. Outreach to local content experts was utilized to clarify pertinent questions.

The next step in adjudication used the NASEM report definition of diagnostic error as a guiding framework to determine if a diagnostic error had occurred. The team classified a case as a diagnostic error if it involved either a failure to diagnose, accurately and timely, the patient's health problem or a failure to appropriately communicate that diagnosis to the patient.[1] Given inherent ambiguity in defining specific measures for "accurate" and "timely," the QI team focused on determining if the error was related to deviation from generally accepted local or national performance standards, if the diagnosis could have reasonably been made based on available information at the time of presentation, and if any diagnostic uncertainty was discussed with the patient or family. Review of the medical encounter documentation, including the provider's medical decision making and patient's discharge instructions, helped determine communication of an uncertain diagnosis.

Study of the Interventions

Consensus decision-making was used to either confirm or refute if a diagnostic error had occurred. All team members present for the monthly meetings provided input during case review to reach a consensus decision supported by the group. If significant disagreement or concerns were present, further case details were obtained, and the case was re-reviewed at the next monthly meeting. Cases confirmed by the QI team to have involved a diagnostic error were included

on the DEI. Cases identified by more than 1 domain (eg, voluntary event report and RCA) were counted only once and categorized in the domain that first reported the error.

Measures

The primary outcome measure was the number of patient cases each month with a diagnostic error confirmed during the adjudication process. The baseline period consisted of confirmed diagnostic errors from January 2016 to December 2016. Cumulative totals were recorded for each domain. Also, the number of cases identified by the 5 domains each month was tracked as a process measure, as this represented the number of cases undergoing adjudication by the diagnostic error QI team.

Analyses

Identified cases and confirmed diagnostic errors were tabulated monthly and tracked on a statistical process control chart. Acknowledging the potential for diagnostic error with every patient encounter across all hospital admissions, surgeries, and outpatient visits, the denominator was deemed sufficiently large and likely consistent over time. Thus, c-charts were used to identify the total count of identified cases and confirmed diagnostic errors occurring each month.[17] Events were recorded based on the month of occurrence. Autopsies were based on the month of patient death. We used the Nelson rules to define special cause variation and to establish a centerline shift.[18]

Ethical Considerations

The NCH Institutional Review Board deemed this project QI research and not human subjects research, so it was exempt from review. Patients were not randomized, and protected health information was not shared outside our institution.

Results

From January 2017 through June 2019, there were 301 cases of potential diagnostic error identified via the five domains. The QI team adjudicated, on average, 10.0 ± 4.8 cases each month. Cases were mostly identified from the abdominal pain trigger tool (43.9%), voluntary reporting (26.6%), and M&M conferences (20.9%), with class I autopsy findings and RCAs accounting for the smallest proportions (5.3% and 3.3%, respectively). There was no special cause variation noted in the monthly number of identified cases over this time (Figure 2).

Of the 301 identified cases, the team determined that a total of 105 cases represented a diagnostic error. The average number of confirmed cases each month was 3.5 ± 2.8.

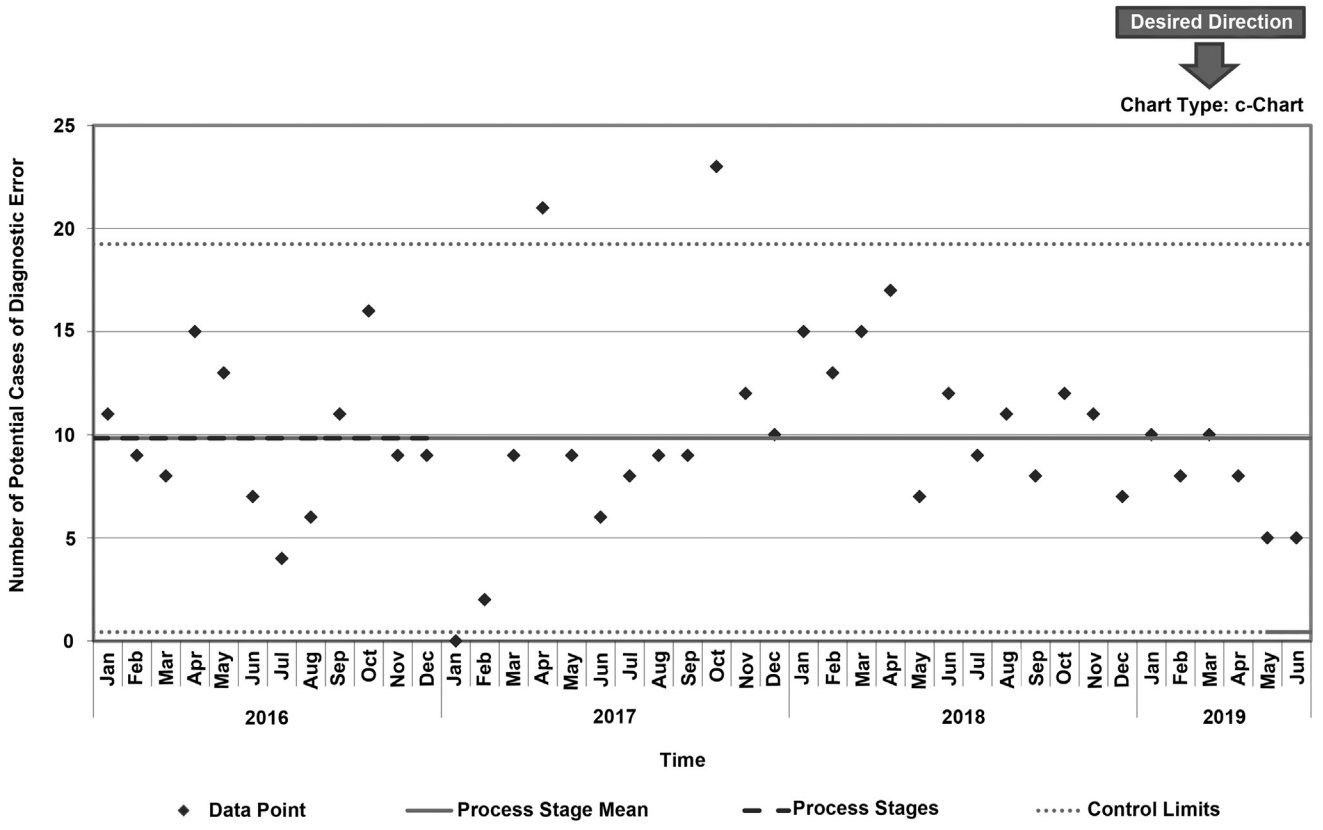

Figure 2. Statistical process control c-chart showing the number of potential cases of diagnostic error each month.

Confirmed diagnostic errors mostly came from M&M conferences (33.3%), voluntary reporting (33.3%), and the abdominal pain trigger tool (24.8%), with the remainder coming from RCAs and class I autopsy findings (7.6% and 1.0%, respectively). The number of diagnostic errors occurring per month decreased from 6.3 during the baseline period to 3.2 by the end of June 2019 (Figure 3). Institutional voluntary reporting submissions and domain reporting rates remained consistent over this time period.

The 105 diagnostic errors were widely distributed, with nearly 60 different diagnoses. The 3 diagnoses most associated with a diagnostic error during the study period included appendicitis (n = 19), missed fractures (n = 10), and nonaccidental trauma (n = 6). Overall, diagnoses associated with the gastrointestinal tract represented 32.4% of confirmed errors. The Table summarizes the main categories of diagnostic errors identified from January 2017 through June 2019 and includes examples of the types of errors represented in each category.

Discussion

We describe a single-center QI project aimed at identifying and measuring diagnostic errors. Although efforts in this area continue to develop, diagnostic error remains an understudied problem at pediatric and adult health institutions.[19-22] However, more organizations are starting to prioritize diagnostic error mitigation efforts given the patient safety implications. Singh et al recently described broad approaches healthcare organizations could implement to improve diagnosis.[23]

Measuring diagnostic error can be a challenging task.[8,24] A multimodal approach and support from executive leadership are essential components for an organization seeking to identify and reduce diagnostic error. Our DEI tool and defined methodology outline a feasible approach to systematically identify diagnostic errors that can be easily translated, with center-specific modifications, to other larger medical institutions.

Using the DEI, we created a reliable methodology to capture diagnostic errors by leveraging pre-existing data sources and minimizing chart review. The 105 confirmed errors represented a broad spectrum of diagnoses. During our study period, appendicitis, fractures, and nonaccidental trauma were the three most likely to have a missed or delayed diagnosis. Previous studies have shown 3.8%-15% of pediatric appendicitis cases are missed at initial presentation.[25-28] Selbst et al conducted a retrospective review using 16 years of closed pediatric insurance claims and found appendicitis and fractures among some of the most common diagnoses involved in malpractice suits.[29] Furthermore, a large children's academic center study found 31.2% of abusive head trauma had been unrecognized by

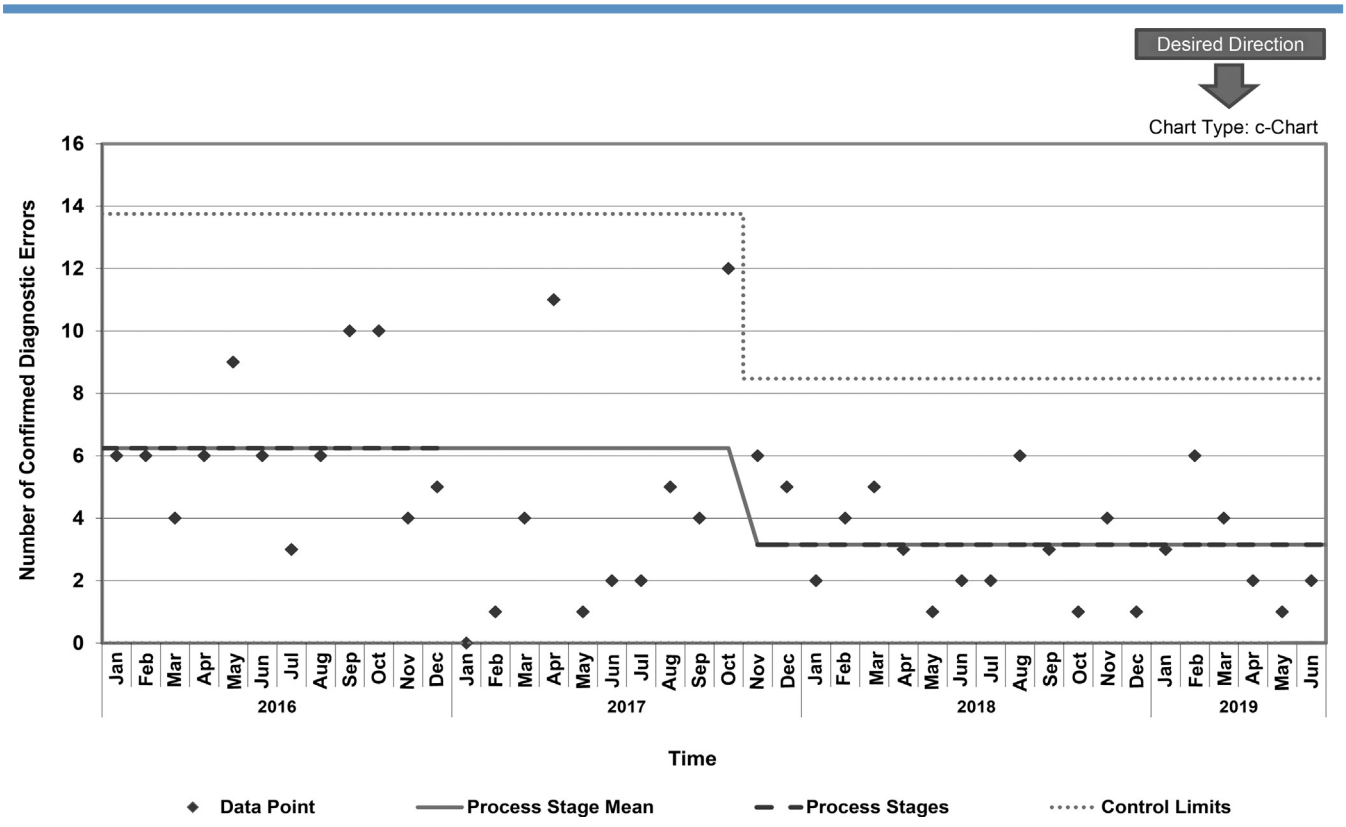

Figure 3. Statistical process control c-chart revealing the number of confirmed diagnosis errors each month.

Table. Classification of confirmed diagnostic errors

Diagnostic error categories	Examples of diagnostic errors	Category percentages (%)
Gastroenterology	Appendicitis	32.4%
	Obstruction	
	Intussusception	
	Constipation	
	Ileus	
	Pancreatitis	
	Hirschsprung disease	
	Superior mesenteric artery syndrome	
	Esophagitis	
Trauma	Fracture	15.2%
	Nonaccidental trauma	
Infectious Disease	Meningitis	14.3%
	Bacteremia	
	Pneumonia	
	Sepsis	
	Osteomyelitis	
Cardiology	Acute heart failure	8.6%
	Congenital heart disease	
	Pericardial effusion	
Vascular	Pulmonary embolus	6.7%
	Stroke	
	Myocardial infarction	
	Subdural hemorrhage	
Oncology	Leukemia	4.8%
	Brain tumor	
	Thrombocytopenia	
Other	Juvenile idiopathic arthritis	20.0%
	Cannabinoid hyperemesis syndrome	
	Hypothyroidism	
	Diabetic ketoacidosis	
	Pregnancy	
	Acute renal failure	
	Graves disease	

physicians.[30] Our study results reiterate that these pediatric diagnoses are among some of the hardest to detect on initial presentation.

Identified cases and confirmed diagnostic errors mostly derived from the abdominal pain trigger tool, M&M conferences, and the voluntary reporting system. These sources each have a defined strength within the DEI. Discrete data elements or triggers, such as our abdominal pain trigger tool, are well-established means for identifying potential patient harm events.[31,32] However, having a tool designed to identify diagnostic error related to abdominal pain likely explains why over 30% of identified errors were related to gastrointestinal tract pathology. Although some chart review is required to clarify these events, by limiting the number of patients to only those that meet specific criteria, the process is quite manageable. As previously mentioned, the M&M conference is an ideal environment to discuss adverse events, review causative factors, provide education, and initiate necessary interventions.[15] Our robust incident reporting system, which identifies hundreds of adverse and near-miss events each month, is a rich source for cases of missed and erroneous diagnoses. Although class I autopsy findings and RCAs contributed to the fewest number of cases, they detect some of the most harmful events and warrant continued inclusion in the DEI.[1,33]

There are several limitations to this project. This study does not account for all diagnostic errors occurring within our hospital system. Instead, we attempted to use preestablished sources to first capture the most significant diagnostic errors. As a single-institution study, our 5 domains identifying potential diagnostic error may not be generalizable to other institutions. However, many institutions have similar data sources, so the conceptual model could be easily reproduced. Also, our institution's receptive and non-punitive safety culture, which promotes the reporting of these events, may be different from other hospitals. Retrospective chart review of cases introduces the potential for hindsight bias, thus our results may have been influenced by non-blinded reviews by our diagnostic error QI team. Finally, we cannot draw significant conclusions regarding the decrease in confirmed diagnostic errors on our statistical process control chart. This shift may be due to initial ongoing interventions. A more detailed analysis of the interventions we implemented is necessary to determine their effect on the incidence of diagnostic error over time.

Our QI team used the NASEM definition to determine if an event should be classified as a diagnostic error. This definition can be ambiguous and open to variable interpretation (eg, what is considered a timely diagnosis for a slow, indolent process such as a malignancy?). Our QI team attempted to mitigate this variability with structured discussions utilizing a consistent multidisciplinary team from diverse backgrounds and specializations.

This QI initiative has laid a foundation to better understand diagnostic errors within our hospital. Our next steps include further classification of confirmed diagnostic errors, focusing on identifying failure modes contributing to each error. We also intend to explore new domains of potential error to move closer to understanding the true incidence of diagnostic error within our institution. Proposed domains have included an EHR trigger tool examining patients with nonspecific complaints who have multiple healthcare encounters or potential diagnostic errors identified through a radiology department peer-review process. With this more complete understanding of the types of diagnostic errors occurring within our institution, we can implement and study directed interventions aimed at diagnostic errors. These interventions include utilizing diagnostic timeouts,[34,35] incorporating clinical decision support software, and promoting more open dialogue and discussions of diagnostic error across the institution.

This DEI is an evolving and modifiable tool that can be adapted at other institutions to identify and measure diagnostic errors. Using 5 well-defined domains and a structured adjudication process, we created a systematic approach to understand the frequency of diagnostic errors and to identify particularly high-risk diagnoses to initiate mitigation efforts. This is only an initial step toward reducing diagnostic error. We hope further refinement of this process will improve health outcomes for our patients and families. ■

Submitted for publication Aug 13, 2020; last revision received Oct 24, 2020; accepted Nov 25, 2020.

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